

REMARKS

Applicant encloses herewith a supplemental information disclosure statement disclosing references first brought to Applicant's attention by a communication from foreign patent office in a counterpart foreign application.

The Examiner has rejected all of the pending claims under 35 U.S.C. § 103(a) over Reed et al. (U.S. Patent No. 5,312,456) or over Reed in view of Fye (U.S. Patent No. 5,031,609) and/or Coates (U.S. Patent No. 4,219,019). In part, the rejections are based on the Examiner's view that the size and configuration of the penetrating elements would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. Claims 1-23 are pending in the application with claim 1 and new claim 19 being the only independent claims.

Applicant respectfully requests reconsideration of the rejection of claims 1-18, in light of the above amendment to claim 1, which now requires "an array of skin penetrating elements extending integrally from the backing to a distal tip, . . . a plurality of [which] each include[e] at least one retention barb extending from an outer side surface of the skin penetrating element, the barb extending laterally from a point spaced below said distal tip." Thus, Applicant's claim 1, as amended, recites a skin penetrating element having a distal tip for penetrating the skin and having a discrete barb provided below the tip for retaining the skin penetrating element in the penetrated skin.

Reed discloses "micromechanical barbs" 16 each having a head 20 and a support 18 extending from a base 22 which may be used to penetrate and adhere to skin. Extremity portions 26 extend from the central portion 24 of head 20 to provide a locking connection with, e.g., the skin. (Col. 3, lines 35-39). Reed's sole disclosed method of making the "micromechanical barbs" is by a photochemical etching process in which layers of different materials are sequentially etched to leave "barbs" of the desired shape. (See Col. 5, lines 39-59 and Col. 6, lines 40-60). In every illustrated embodiment, the extensions of Reed's barbs extend from the extreme upper end of the barbs as an integral part of the upper layer of the substrate from which they are micromachined.

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By spacing the barbs below the penetrating end of each element, the aspect of the invention recited in claim 1 enables the tips to readily penetrate the outer skin layer before encountering any resistance from engagement of the barbs with the skin.

Fye and Coates disclose bandages of various materials (e.g., nylon and polyethylene terephthalate, respectively). However, neither reference overcomes the above-described deficiencies of Reed as concerning amended claim 1.

Applicant's new independent claim 19 recites a skin attachment member having "an array of skin penetrating elements . . . a plurality of [which] each include[e] at least one retention barb extending from an outer side surface . . . wherein said array of skin penetrating elements, including each retention barb, is molded integrally from a single plastic resin."

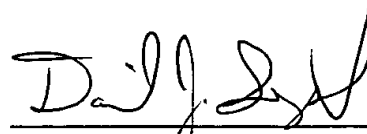
The skin attachment member of claim 19 is structurally distinct from that disclosed by Reed, in that Reed does not teach or suggest a skin penetrating element with a barb made integrally of a single plastic resin. Reed's disclosed photochemical etching process does not enable one of ordinary skill in the art to produce the homogenous structure required by claim 19.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a check for excess claims fee, please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

Claims 1-12 and 17 have been amended as follows:

1. (Amended) A skin attachment member of plastic resin, comprising:
a sheet-form backing, and
an array of skin penetrating elements extending integrally from the backing to a distal tip,
the skin penetrating elements being configured to penetrate into the epidermal skin layer and
sized to limit painful contact with nerves below the epidermal skin layer,
[at least many] a plurality of the skin penetrating elements each including at least one
retention barb extending from an outer side surface of the skin penetrating element, the barb
extending laterally from a point spaced below said distal tip and, the barbs] configured to
cooperate to resist removal of the skin attachment member from skin.
2. (Amended) The skin attachment member of claim 1 wherein each skin penetrating
element comprises a cone-shaped body.
3. (Amended) The skin attachment member of claim 2 wherein a base of the cone-shaped
body has a diameter of about 0.003["] inch (0.08 mm).
4. (Amended) The skin attachment member of claim 1 wherein said distal tip of each
skin penetrating element [includes a pointed tip] has a pointed shape.
5. (Amended) The skin attachment member of claim 1 wherein each skin penetrating
element has a length of about 0.012["] inch (0.3 mm).
6. (Amended) The skin attachment member of claim 1 wherein the backing has a
thickness in a range of about 0.003["] to 0.008["] inch (0.08 to 0.2 mm).

7. (Amended) The skin attachment member of claim 1 wherein the at least one retention barb of each of said plurality of skin penetrating elements is located about 0.008["] to 0.0095["] inch (0.2 to 0.24 mm) along a length of the skin penetrating element from the backing.

8. (Amended) The skin attachment member of claim 1 wherein the at least one retention barb of each of said plurality of said skin penetrating elements has a length of about 0.0001["] inch (0.003 mm).

9. (Amended) The skin attachment member of claim 1 wherein the at least one retention barb of each of said plurality of skin penetrating elements tapers from a thickness of about 0.0001["] inch (0.0003 mm) to a point at an angle of about 72[E] degrees.

10. (Amended) The skin attachment member of claim 1 wherein [of] each of said plurality of skin penetrating elements includes two of said barbs.

11. (Amended) The skin attachment member of claim 1 having a density of about 400 skin penetrating elements in a 0.1 [in²] inch² (65 mm²) area.

12. (Amended) The skin attachment member of claim 1 wherein the skin penetrating elements are spaced apart from each other a distance of about 0.003["] inch (0.08 mm).

16. (Amended) The skin attachment member of claim 1 [formed by molding] wherein the sheet-form backing and the skin penetrating elements, including each barb, are molded integrally of a single plastic resin.

17. (Amended) The skin attachment member of claim 1 wherein [at least many] a plurality of the skin penetrating elements each define at least one groove in [an] said outer side surface [of the skin penetrating elements].